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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,768	11/06/1998	ANTHONY H. CINCOTTA	2991/1B206-U	3476

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/22/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/187,768

Applicant(s)

CINCOTTA ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-47, 49-54, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-47, 49-54, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Response to Arguments

The Remarks filed July 29, 2002 (Paper No. 20) in response to the Office Action of January 29, 2002 are acknowledged and have been entered into the record.

Claims 34-47, 49-54, and 59-60 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained

Double-Patenting:

Claims 34-36, 39, 43, 49, 59-60 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7-8, and 13 of U.S. Patent No. 5,792,748 in view of Werning et al. (Arch. Otolaryngol. Head Neck Surg., July 1995, v121, pp. 783-789, IDS) and Cincotta et al. (Cancer Research, 1994, Vol. 54, pp. 1249-1258, IDS), as further evidenced by Molitch, ME (Endocrinol. Metab. Clin. North. Am., 1992, Vol. 21(4), Abstract only) for the reasons of record.

Further, Claims 34-36, 39, 43, 49, and 59-60 remain directed to an invention not patentably distinct from claims 3, 7-8, and 13 of commonly assigned U.S. Patent No. 5,792,748, for the reasons set forth previously and above.

The assignee has not demonstrated that the conflicting inventions were commonly owned at the time the invention in this application was made.

Claims 34-37, 43, 49, and 59 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-13 and 28, 30 of U.S. Patent No. 6,071,914 in view of Werning et al. (Arch. Otolaryngol. Head Neck Surg., July 1995, v121, pp. 783-789, IDS) and Cincotta et al. (Cancer Research, 1994, Vol. 54, pp. 1249-1258, IDS), as further evidenced by Molitch, ME (Endocrinol.Metab.Clin.North.Am., 1992, Vol. 21(4), Abstract only).

Claims 34-37, 43, 49, and 59 remain directed to an invention not patentably distinct from claims 12-13 and 28, 30 of commonly assigned U.S. Patent No. 6,071,914 as applicants have shown (Paper No. 20, page 8) that the conflicting inventions were NOT commonly owned at the time the invention in this application was made.

35 USC 103

Claims 34-47, 49-54, and 59-60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cincotta et al. (**US Patent No. 5,792,748 and/or US Patent 6,071,914**) in view of Werning et al. (Arch. Otolaryngol. Head Neck Surg., July 1995, v121, pp. 783-789, IDS) and Cincotta et al. (Cancer Research, 1994, Vol. 54, pp. 1249-1258, IDS), as further evidenced by Molitch, ME (Endocrinol.Metab.Clin.North.Am., 1992, Vol. 21(4), Abstract only) for the reasons of record.

Applicants reiterate (Paper No. 20, page 3) that one of ordinary skill in the art would not find any motivation to combine either the claims or specification of the '748 patent or '914 patent with Werning *et al.*, as evidenced by Molitch.

Applicants begin by pointing out that the instant claims are not merely drawn to treating tumors by administration of a prolactin enhancer and PDT. The claims are rather drawn to PDT in combination with "adjusting the daily plasma prolactin profile of the tumor bearing mammal to approach the profile of a normal mammal, by administering a prolactin enhancer at appropriate time intervals". This point is considered moot as the content of the claims was thoroughly compared with the teachings of the prior art in the prior office actions.

Applicants further argue that prolactin is not mentioned once in Werning *et al.*, and that contrary to the Examiner's assertion, Werning *et al.* never recite "prolactin enhancer". Instead, Werning *et al.* teach that "metoclopramide hydrochloride" improves PDT in nude mice. This argument has been considered but is not found persuasive for the reasons of record in Paper No. 18, pages 3-4. Moreover, despite the fact that Werning *et al.* may not refer to metoclopramide as a "prolactin enhancer", it was not incorrect to refer to metoclopramide, as a prolactin enhancer because it was well known in the art at the time the invention was made that metoclopramide, is a prolactin enhancer as evidenced in the record by Molitch.

Applicants also argue (Paper No. 20, page 5) that Werning *et al.* teaches away from resetting the prolactin profile of the tumor bearing mammal to approach the prolactin profile of a normal mammal because the references which have been cited teach that the effect of metoclopramide is NOT through its effects on prolactin. Applicants further argue that the dosages recited in Werning are contrary to the teachings of the '748 patent and the '914 patent.

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Applicants argue that the type of administration as taught in Werning would lead to uniformly high levels of plasma prolactin. Applicants further argue that adjusting the plasma prolactin profile of a tumor bearing mammal to approach the profile for a normal mammal “requires that a prolactin enhancer not be administered to maximize prolactin levels”. This argument has been considered but is not found persuasive. On the contrary, the presently claimed subject matter is drawn to the administration of a prolactin enhancer in a tumor bearing mammal. Further, there is no explicit teaching away either in the references or in the state of the art which would suggest to one of ordinary skill in the art not to combine the teachings. The motivation to combine the teachings has been clearly delineated in the prior actions as well as the obvious differences between the references cited. For these reasons, and the reasons of record, applicant’s arguments are not found persuasive and the rejections are maintained.

Applicants further argue (Paper No. 20, page 7) that the unexpected results as set forth in Example 2 of the specification are nonobvious. This argument has been considered but is not found persuasive as Werning *et al.* have disclosed unexpected results by combining PDT with metoclopramide (a prolactin enhancer) in that 100% tumor regression without re-growth was observed. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Gary B. Nickol, Ph.D.

Examiner

Art Unit 1642

GBN

October 9, 2002


ANTHONY C. CAPUTO
SUPERVISOR, PATENT EXAMINER
OCT 10 2002